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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/993,808	11/06/2001	William J. Gordon-Kamm	1146	8538

27310 7590 07/06/2005

PIONEER HI-BRED INTERNATIONAL INC.
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EXAMINER

COLLINS, CYNTHIA E

ART UNIT PAPER NUMBER

1638

DATE MAILED: 07/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/993,808

Applicant(s)

GORDON-KAMM ET AL.

Examiner

Cynthia Collins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-80 is/are pending in the application.
- 4a) Of the above claim(s) 12 and 14-78 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-11, 13, 79 and 80 is/are rejected.
- 7) ☒ Claim(s) 2 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☒ Other: See Continuation Sheet.

S-0-0

Continuation of Attachment(s) 6). Other: Raw Sequence Listing Error Report and Notice to Comply..

DETAILED ACTION

The Amendment filed January 31, 2005 has been entered.

Claim 1 is cancelled.

Claims 79-80 are newly added.

Claims 2-80 are pending.

Claims 2-5, 10-11 and 13 are currently amended.

Claim 12 and 14-78 are withdrawn.

Claims 2-11, 13 and 79-80 are examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

Specification

A computer readable form (CRF) of the sequence listing was submitted January 31, 2005. However, the Scientific and Technical Information Center (STIC) detected errors when processing the CRF as set forth on the attached Raw Sequence Listing Error Report and Notice to Comply.

Claim Rejections - 35 USC § 112

Claims 3-11 remain rejected, and claims 79-80 are rejected, under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably

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convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the office action mailed October 26, 2004.

Applicant's arguments filed January 31, 2005 has have been fully considered but they are not persuasive.

Applicants traverse the rejection and point out that the application presents three sequences that bind to CDK. Applicants point out that the percent identity between SEQ ID NO: 1 and SEQ ID NO: 3 is 71%, and that the percent identity between SEQ ID NO: 1 and SEQ ID NO: 5 is 89%. Applicants also point out that specification identifies the cyclin binding domains of three sequences on page 49, lines 18-23. Applicants additionally point out that the specification also identifies a second conserved domain on page 49 lines 15-18. (reply page 16)

The Examiner maintains that the rejected claims do not require that the sequences encode polypeptides that bind to any particular class of cyclin-dependent kinase or exhibit any other type of specific function. The Examiner also maintains that SEQ ID NO: 3 does not support the description of the claimed genus, as the claimed genus is limited to polynucleotide sequences having at least 80% sequence identity to SEQ ID NO: 1, which excludes sequences having 71% identity to SEQ ID NO: 1. The Examiner further maintains that the disclosure of a single additional sequence obtained from maize that has 89% identity to SEQ ID NO: 1 (the additional sequence of SEQ ID NO: 5) is not sufficient to support the description of a genus of polynucleotides obtained from any unspecified source that encode polypeptides having any unspecified type of cyclin-dependent kinase binding region.

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With respect to the binding domains of three sequences identified on page 49, the Examiner first maintains that the rejected claims do not require the presence of any cyclin binding domain; the rejected claims require only that the encoded polypeptide have a “cyclin-dependent kinase binding region” of unspecified structure and function. The Examiner also maintains that the specification describes the binding domains of three sequences as differing in structure: CKI B (SEQ ID NO:2)-EFFYEMQAKRFASKYNFDFVRGVPLDAGGRFEWAPWSI (SEQ ID NO:10); CKI C (SEQ ID NO:4)-EYFMEQRRQQQDFIDKYNFDPANDCPLPGRFEYKLDI (SEQ ID NO:11); and CKI D (SEQ ID NO:6) AQEIQEFFFWEMHAKRFASKYNFDFVRGVPLDAGRFEYPGVSI (SEQ ID NO:12) and function (CDK binding and/or cyclin binding). The Examiner further maintains that the disclosure of a single additional sequence obtained from maize that has 89% identity to SEQ ID NO:1 and that encodes a polypeptide having a binding domain that is structurally distinct from the binding domain of the polypeptide encoded by SEQ ID NO:1 is not sufficient to support the description of a genus of polynucleotides obtained from any unspecified source that encode polypeptides having any unspecified type of cyclin-dependent kinase binding region.

With respect to the second conserved domain identified on page 49, the Examiner maintains that the rejected claims do not require the presence of SEQ ID NO:7 (MGKYM RK) at the 5' end of the encoded polypeptides.

Applicants further point to the representative number requirement as addressed by the USPTO in the Written Description Guidelines, and note that the Guidelines provide that there may be situations where one species adequately supports a genus. Applicants point out that the

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Guidelines further state that satisfactory disclosure of a "representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed, and maintain that since the present claims require 80% identity to SEQ ID NO: 1, the claims do not read on "widely variant species" and therefore do not require a laundry list of potential sequences. Applicants maintain that one of skill in the art would therefore recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. (reply pages 16-17)

The Examiner disagrees with the assessment that a genus requiring 80% identity to SEQ ID NO: 1 does not have substantial variation, as SEQ ID NO:1 is 1372 nucleotides in length, such that the claimed genus encompasses sequences that can differ from SEQ ID NO:1 by as many as 274 unspecified nucleotides. One of skill in the art would therefore would not recognize from the disclosure of only SEQ ID NOS: 1 and 5 that applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus.

Claims 3-11 remain rejected, and claims 79-80 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid comprising a polynucleotide that encodes a polypeptide of SEQ ID NO: 2, as well as an expression cassette comprising a polynucleotide that encodes a polypeptide of SEQ ID NO: 2 operably linked to a promoter wherein the nucleic acid is in a sense orientation, a host cell and transgenic plant and seed comprising said expression cassette, does not reasonably provide

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enablement for other polynucleotide sequences, or for expression cassettes comprising a polynucleotide that encodes a polypeptide of SEQ ID NO: 2 operably linked to a promoter wherein the nucleic acid is in an antisense orientation. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, for the reasons of record set forth in the office action mailed October 26, 2004.

Applicant's arguments filed January 31, 2005 has have been fully considered but they are not persuasive.

Applicants traverse the rejection and point to page 18 of the specification which cites the references Sheehy et al. Proc. Nat'l. Acad. Sci. (USA) 85:8805-8809 (1988) and U.S. Patent No. 4,801,340. Applicants also point to the Examples located on pages 42-47. Applicants maintain that one of ordinary skill in the art is able to use the SEQ ID NO: 1 in an antisense orientation in view of the disclosure. (reply pages 17-18)

The cited references of Sheehy et al. and U.S. Patent No. 4,801,340 do not enable the full scope of the claimed invention, as neither Sheehy et al. nor U.S. Patent No. 4,801,340 provide any guidance with respect to which structural elements of SEQ ID NO:1 would be retained by variants that function in the same manner as SEQ ID NO:1 or whose specific function differs from that of SEQ ID NO:1. The Examples located on pages 42-47 also do not enable the full scope of the claimed invention, as the prophetic examples do not provide sufficient guidance with respect to which structural elements of SEQ ID NO:1 would be retained by variants that function in the same manner as SEQ ID NO:1 or whose specific function differs from that of SEQ ID NO:1. Such guidance is necessary because the functionality of variants of

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SEQ ID NO:1 is unpredictable, since structurally homologous amino acid sequences are not always functionally homologous.

The cited references of Sheehy et al. and U.S. Patent No. 4,801,340 also do not enable the full scope of the claimed invention, as neither Sheehy et al. nor U.S. Patent No. 4,801,340 provide any guidance with respect to how to use SEQ ID NO:1 to make antisense expression cassettes that function in a specific manner. The Examples located on pages 42-47 also do not enable the full scope of the claimed invention, as the prophetic examples do not provide sufficient guidance with respect to how to use SEQ ID NO:1 to make antisense expression cassettes that function in a specific manner. Such guidance is necessary because making and using antisense expression cassettes is unpredictable, as the ability of an antisense transcript to suppress gene expression depends on multiple variables which include but are not limited to the length of the antisense transcript, its position relative to the parent gene, and the degree of homology between the antisense transcript and the gene to be suppressed.

Claim Rejections - 35 USC § 101

Claim 12 is rejected under 35 USC 101 because the claimed invention is directed to non-statutory subject matter.

Claim 12, as amended, does not sufficiently distinguish over ribonucleic acids as they exist naturally, because the claim does not particularly point out any non-naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See Diamond v. Chakrabarty, 447 U.S. 303, 206 USPQ 193 (1980).

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The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "Isolated" or "Purified". See MPEP 2105.

Allowable Subject Matter

Claim 2 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form and limited to SEQ ID NO:1.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Remarks

No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cynthia Collins
Examiner
Art Unit 1638

CC


6/29/05

Notice to Comply

Application No.

09/993,808

Examiner

Cynthia Collins

Applicant(s)

GORDON-KAMM ET AL.

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NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- ☐ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).
- ☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- ☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- ☒ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- ☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- ☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- ☐ 7. Other:

Applicant Must Provide:

- ☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- ☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- ☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216

For CRF Submission Help, call (703) 308-4212

PatentIn Software Program Support

Technical Assistance.....703-287-0200

To Purchase PatentIn Software.....703-306-2600

PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR REPLY

STIC Biotechnology Systems Branch

RAW SEQUENCE LISTING **ERROR REPORT**

The Biotechnology Systems Branch of the Scientific and Technical Information Center (STIC) detected errors when processing the following computer readable form:

Application Serial Number: 09/993,808C
Source: IFW/b
Date Processed by STIC: 2/7/05

THE ATTACHED PRINTOUT EXPLAINS DETECTED ERRORS.

PLEASE FORWARD THIS INFORMATION TO THE APPLICANT BY EITHER:

- 1) INCLUDING A COPY OF THIS PRINTOUT IN YOUR NEXT COMMUNICATION TO THE APPLICANT, WITH A NOTICE TO COMPLY or,
- 2) TELEPHONING APPLICANT AND FAXING A COPY OF THIS PRINTOUT, WITH A NOTICE TO COMPLY

FOR CRF SUBMISSION AND PATENTIN SOFTWARE QUESTIONS, PLEASE CONTACT MARK SPENCER, TELEPHONE: 571-272-2510; FAX: 571-273-0221

TO REDUCE ERRORED SEQUENCE LISTINGS, PLEASE USE THE **CHECKER VERSION 4.2.2 PROGRAM**, ACCESSIBLE THROUGH THE U.S. PATENT AND TRADEMARK OFFICE WEBSITE. SEE BELOW FOR ADDRESS:

<http://www.uspto.gov/web/offices/pac/checker/chkrnote.htm>

Applicants submitting genetic sequence information electronically on diskette or CD-Rom should be aware that there is a possibility that the disk/CD-Rom may have been affected by treatment given to all incoming mail. Please consider using alternate methods of submission for the disk/CD-Rom or replacement disk/CD-Rom. Any reply including a sequence listing in electronic form should NOT be sent to the 20231 zip code address for the United States Patent and Trademark Office, and instead should be sent via the following to the indicated addresses:

1. EFS-Bio (<<http://www.uspto.gov/ebc/efs/downloads/documents.htm>> , EFS Submission User Manual - ePAVE)
2. U.S. Postal Service: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450
3. Hand Carry, Federal Express, United Parcel Service, or other delivery service (EFFECTIVE 01/14/05): U.S. Patent and Trademark Office, Mail Stop Sequence, Customer Window, Randolph Building, 401 Dulany Street, Alexandria, VA 22314

Revised 01/24/05



IFW16

RAW SEQUENCE LISTING

DATE: 02/07/2005

PATENT APPLICATION: US/09/993,808C

TIME: 17:40:38

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4 <110> APPLICANT: Gordon-Kamm, William
 5 Lowe, Keith
 6 Sun, Yuejin
 7 Dilkes, Brian
 8 Larkins, Brian
 11 <120> TITLE OF INVENTION: Cell Cycle Nucleic Acids, Polypeptides,
 12 and Uses Thereof
 14 <130> FILE REFERENCE: 1146
 C--> 16 <140> CURRENT APPLICATION NUMBER: US/09/993,808C
 C--> 16 <141> CURRENT FILING DATE: 2001-11-06
 E--> 16 <160> NUMBER OF SEQ ID NOS: 612(p.3)
 18 <170> SOFTWARE: FastSEQ for Windows Version 3.0

ERRORED SEQUENCES

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 117 <223> OTHER INFORMATION: Xaa = Any Amino Acid
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 123 20 25 30
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 125 35 40 45
 126 Arg Ala Pro Ala Gly Glu Pro Ala Ala Ala Val Ser Ala Gly Gly Asp
 127 50 55 60
 128 Gly Gly Ser Cys Tyr Ile His Leu Arg Ser Arg Met Leu Phe Met Ala
 129 65 70 75 80
 130 Pro Pro Gln Pro Gln Pro Ser Val Asp Ser Val Pro Thr Pro Val Glu
 131 85 90 95
 132 Ala Ala Asp Gly Ala Ala Gly Gln Gln Gly Ala Ala Leu Ala Ala Gly
 133 100 105 110
 134 Leu Ser Arg Cys Ser Ser Thr Ala Ser Ser Val Asn Leu Gly Leu Gly
 135 115 120 125
 136 Gly Gln Arg Gly Ser His Thr Cys Arg Ser Tyr Asp Ala Ala Glu Ala
 137 130 135 140

pp 1-3
 Does Not Comply
 Corrected Diskette Needed

RAW SEQUENCE LISTING

DATE: 02/07/2005


PATENT APPLICATION: US/09/993,808C

TIME: 17:40:38

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Output Set: N:\CRF4\02072005\I993808C.raw

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142 His Gly Glu Leu Ser Asp Leu Glu Ser Asp Leu Ala Gly His Lys Thr
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145 195 200 205
146 Pro Ala His Glu Ile Gln Glu Phe Phe Ala Ala Ala Glu Ala Ala Gln
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09/993,808C 3

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		20					25						30		
Leu	Asp	Ala	Gly	Arg	Phe	Glu	Trp	Thr	Pro	Gly	Val	Ser	Ile		
		35				40						45			

FYI

Use of n and/or Xaa has been detected in the Sequence Listing.
Review the Sequence Listing to insure a corresponding
explanation is presented in the <220> to <223> fields of
each sequence using n or Xaa.

VERIFICATION SUMMARY

DATE: 02/07/2005

PATENT APPLICATION: US/09/993,808C

TIME: 17:40:40

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Output Set: N:\CRF4\02072005\I993808C.raw

L:16 M:270 C: Current Application Number differs, Replaced Current Application No
L:16 M:271 C: Current Filing Date differs, Replaced Current Filing Date
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L:299 M:258 W: Mandatory Feature missing, <223> Tag not found for SEQ ID#:5
L:299 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:5 after pos.:512
L:354 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:6 after pos.:96
L:394 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:8 after pos.:0
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